

REQUEST FOR SINGLE PROJECT ASSURANCE NEGOTIATION
(For Use By IRB Chairs Only)

Date:

Subject: Collaborative Research by Intramural Investigators Involving Human Subjects

To: OPRR, Division of Human Subjects Protection, Bldg. 61E/3B01

Through: Office of Human Subjects Research, Bldg. 10/1C-116

From: _____, Chair
(ICD)

Intramural investigators in _____(ICD) are participating in the following study that involves human subjects. My review suggests that this study requires a Single Project Assurance (SPA). I am providing the following information so that you can proceed with the negotiation as you determine appropriate. Enclosed are the documents ** that I have received concerning this study which has received full/expedited review. Please send me a copy of the completed SPA for the IRB files, or a notification that you have determined that no SPA is necessary.

Name of Research Study:

Protocol Number (if any): _____

Name of Intramural Principal Investigator (PI): _____

Building, Room, Telephone and FAX Number of PI: _____

Names, Telephone and FAX Numbers of Responsible Investigator(s) at
Collaborating Institution(s):

Name(s) of Collaborating Institution(s), including full mailing address:

Check below as appropriate:

☐ The study was reviewed & approved by the full IRB on _____(date).
If with stipulations, the stipulations were met on _____(date).

☐ The study was approved by expedited review on _____(date).

☐ The study will be reviewed by the IRB on _____(date); concomitant SPA negotiation requested.

** (1) Documents required for studies that have had (will have) full IRB review: One copy of the complete protocol, including the consent form.
(2) Documents required for studies that have had expedited review: Copy of complete protocol or memorandum from the P.I. to the IRB Chair describing the study, including a consent document, if available, plus the IRB Chair's response.